UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,292	11/25/2003	Richard A. Shimkets	11669.206USD1	9115

23552 7590 06/14/2006

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,292	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 27-30, and 47, drawn to a protein, and a pharmaceutical composition comprising a protein, classified in class 530, subclass 350.

II. Claims 9-10, 35 and claim 46 in part as it applies to a kit comprising an antibody, drawn to an antibody, and a pharmaceutical composition comprising the same, classified in class 530, subclass 387.1.

III. Claims 11-26, 31-34, and 46 in part as it applies to a kit comprising nucleic acids, drawn to an isolated nucleic acid, a recombinant cell containing the same, a method of producing a protein comprising the recombinant cell, and a pharmaceutical composition comprising a nucleic acid or recombinant cell, classified in class 536, subclass 23.1.

IV. Claims 36-39, drawn to methods of treatment comprising administration of a molecule that promotes function of a protein or rRNA, classifiable in class 514, subclass 44.

V. Claims 40-42, drawn to drawn to methods of treatment comprising administration of a molecule that inhibits function of a protein, classifiable in class 424, subclass 130.1.

VI. Claims 43-45, drawn to methods of diagnosing a disease or a predisposition to developing a disease, classifiable in class 435, subclass 6.

VII. Claim 48, drawn to a method for identifying a molecule that binds to a ligand, classified in class 436, subclass 501.

VIII. Claim 49, drawn to a recombinant non-human animal, classified in class 435, subclass 325.

Requirement for further restriction

If applicant elects the invention of Group I, applicant is required to further select **a single protein** from the group consisting of CH-1, CH-2, CH-3, CH-4, CH-5, CH-6, CH-7, CH-8, and CH-9. Applicant is also required to select for examination a single SEQ ID NO: from SEQ ID NOs: 1-9 (as recited in claim 3); the selected SEQ ID NO should correspond to the selected protein. This is not an election of species. The claims will be examined only insofar as they require the selected protein.

If applicant elects the invention of Group II, applicant is required to further select **a single protein for binding specificity** from the group consisting of CH-1, CH-2, CH-3, CH-4, CH-5, CH-6, CH-7, CH-8, and CH-9. This is not an election of species. The claims will be examined only insofar as they require the antibody with the selected binding specificity.

If applicant elects the invention of Group III, applicant is required to further select **a single encoded protein** from the group consisting of CH-1, CH-2, CH-3, CH-4, CH-5, CH-6, CH-7, CH-8, and CH-9. Applicant is also required to select for examination a

single SEQ ID NO: from SEQ ID NOs: 1-9 (as recited in claims 15 and 16); the selected SEQ ID NO: should correspond to the selected protein. This is not an election of species. The claims will be examined only insofar as they require the nucleic acid encoding the selected encoded protein.

If applicant elects the invention of Group IV, applicant is required to further select **a single target** of the therapeutic agent selected from the group consisting of CH-1, Desmin, Protein Kinase C-Binding Protein B15, 5.8S rRNA, 18S rRNA, and 28S rRNA (as recited in claim 36). Applicant shall also select a single type of molecule for therapy from either protein or nucleic acid, as recited in claim 39. This is not an election of species. The claims will be examined only insofar as they require a treatment method that targets the selected element.

If applicant elects the invention of Group V, applicant is required to further select **a single target** of the therapeutic agent selected from the group consisting of CH-2, CH-31, CH-4, CH-5, CH-6, CH-7, CH-9, a-Enolase, Antizyme Inhibitor, Biglycan, Cytochrome Oxidase I, Cytochrome Oxidase II, Cyclin G, D-binding protein, Fibrillin, Laminin a-1, p85 and Preproenkephalin (as recited in claim 40). Applicant shall also select a single type of molecule for therapy from either antibody, antisense, or nucleic acid, as recited in claim 41. This is not an election of species. The claims will be examined only insofar as they require a treatment method that targets the selected element.

If applicant elects the invention of Group VI, applicant is required to further select **a single analyte type** for measurement selected from either RNA or protein. Applicant

shall further select **a single specific analyte** selected from the group consisting of CH-1, Desmin, Protein Kinase C-Binding Protein B15, 5.8S rRNA, 18S rRNA, and 28S rRNA, CH-2, CH-31, CH-4, CH-5, CH-6, CH-7, CH-9, a-Enolase, Antizyme Inhibitor, Biglycan, Cytochrome Oxidase I, Cytochrome Oxidase II, Cyclin G, D-binding protein, Fibrillin, Laminin a-1, p85 and Preproenkephalin (as recited in claims 44 and 45). This is not an election of species. The claims will be examined only insofar as they require a diagnosis method that analyzes the selected element.

If applicant elects the invention of Group VII, applicant is required to further select **a single particular ligand** from the group consisting of protein or nucleic acid. Applicant shall also further select **a single gene** from the group consisting of CH-1, CH-2, CH-3, CH-4, CH-5, CH-6, CH-7, CH-8, and CH-9. This is not an election of species. The claims will be examined only insofar as they require a molecule identification method that comprises the selected protein.

If applicant elects the invention of Group VIII, applicant is required to further select **a single particular gene** from the group consisting of CH-1, CH-2, CH-3, CH-4, CH-5, CH-6, CH-7, CH-8, and CH-9. This is not an election of species. The claims will be examined only insofar as they require arecombinant animal that comprises inactivation of the selected gene.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of groups I, II III, and VIII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid

of Group III is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops. They are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein as evidenced by the methods of at least Group VII. The antibody of Group II is also composed of amino acids linked in peptide bonds and arranged spatially in a specific tertiary structure that allows the antibody to specifically bind to particular regions (i.e. epitopes) of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) are associated via disulfide bonds into a Y-shaped symmetric dimer. The recombinant animal of the invention of Group VIII is an organism composed of structurally and functionally complex biological systems, thus different from the isolated proteins, antibodies, and nucleic acids of Groups I, II, and III. Furthermore, the products of Group I, II, and III can be used in materially different processes, for example, the nucleic acids of Group III can be used in hybridization assays, the antibody of Group II can be used in immunoassay, and the polypeptide of Group I can be used to make fusion protein with an enzymatic function, and the animal of Group VIII can be used a model system for analysis of novel therapeutics. Consequently, the reagents, reaction conditions, and reaction parameters

required to make or use each invention are different. Therefore, the inventions of Groups I, II, III and VIII are patentably distinct from each other.

3. Inventions I (protein) and IV, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of the inventions of groups IV, VI, and VII can be performed using nucleic acids instead of protein molecules.

4. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Group V does not require the protein of Group I.

5. Inventions II and IV, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of Groups IV, VI, and VII netiher recite nor require the antibody of Group II.

6. Inventions II (antibody) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case the method of the invention of group V can be performed using nucleic acids instead of antibody molecules.

7. Inventions III (nucleic acids) and IV, V, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of the inventions of groups IV, VI, and VII can be performed using proteins instead of nucleic acid molecules, and the method of Group V may be performed using antibodies.

8. The methods of inventions IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different effects: The methods of Group IV promote the function of a protein or rRNA, Group V inhibits function of a protein, Group VI diagnoses a disease, and Group VII identifies a molecule. Additionally the different methods can be performed using different reagents of protein, antibodies, and nucleic acids.

9. The Invention of Group VIII (recombinant animal) and IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and

effects (MPEP § 802.01 and § 806.06). In the instant case, none of the methods of Groups and IV, V, VI, and VII recite or require the recombinant animal of Group VIII.

10. Regarding the requirements for further restriction, the different biological molecules (different named genes and SEQ ID NOs) are unique elements that are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C 121. The search and examination of all possible groups and all possible sequences would pose an enormous burden on the examiner and on the PTO search resources.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter due to all of the inventions' different gene sequences would require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore the restriction is deemed proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented

prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER